Organ Transplantation in China and Beyond

ORGAN TRANSPLANTATION IN CHINA AND BEYOND: ADDRESSING THE 'ACCESS GAP'

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Abstract: While we may be on the verge of a very exciting sci-tech era, many millions of people will fail to benefit from advances, just as millions already fail to reap the benefits of recent and not-so-recent developments in medical practices. An example of such an under-experienced innovation is organ and tissue transplantation, a field in which demand far exceeds supply in every country in the world. This is not because transplant techniques are particularly new, risky, or experimental. On the contrary, they are well understood and becoming routinised. This paper examines the social and cultural factors surrounding the recent implementation of a new legal regime governing transplantation in China. In particular, it considers how far this model can or could address a perennial problem associated with new and emerging (health) technologies, namely equitable access. Currently, very few people benefit from our understanding of, and growing capabilities in, organ and tissue transplantation (as well as other health advances). The paper then considers actions which ought to be taken to improve transplant medicine in China and beyond; actions which could improve public medicine dramatically.

INTRODUCTION

It is perhaps obvious that we are at the very fringes—the leading edge—of a sci-tech era that will be dominated by high technology solutions to social and technical problems, with implications of global, regional, local, and personal scales. A host of disciplines, including physics, engineering, and biology, are experiencing rapid evolutions, particularly the latter, which now contains sub-disciplines with genetic, engineering, synthetic, and nano-scale elements. What is less obvious, however, is whether much of humanity will benefit from these advances. While all manner of experimental medical innovations are pushing the boundaries of our preventative and curative capacities, many are expensive and imperfect; not at all ready to enter over-burdened or newly developed public healthcare systems. More troubling is that processes and procedures which are not experimental, but which are rather demonstrably effective, are not at all being deployed to maximum benefit. One such process is organ and tissue transplantation, or at least transplantation of certain organs and tissue.

Obviously, success rates vary depending on the nature of the transplantation, and transplantations are often complex surgeries with concomitant risks, but the challenges are

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generally well understood and can often be managed. Progress in medical science, surgical techniques, immunosuppressant drugs, and post-operative care since the first organ transplantation in 1954 (a kidney transplant between twin brothers) have mainstreamed transplantation in many health systems, making it *reasonably* routine and reliable.[1] The first Chinese transplantation took place in 1969. Practices improved dramatically through the 1980s and '90s. Hearts, lungs, livers, kidneys, pancreases, bones, skin and corneas are all now capable of transplantation in China, most with reasonably good 1-year and 5-year post-operative patient survival rates.[2] And the development of one of the largest transplantation programmes in the world together with recent national debates and reforms in China have encouraged greater ties with the international transplantation community, and China is expecting to benefit from this circumstance.[3]

Nonetheless, despite existing capabilities, the majority of people who could benefit from (if not be cured by) transplantation languish under the burden of their conditions, and die. For example, 1-1.5 million Chinese patients require transplantations annually, but only 11,000-13,000 transplantations are conducted.[4] Over 100,000 patients suffer kidney failure annually, but only some 2,000 kidneys are available.[5] Approximately 5 million patients suffer from blindness, of which some 30,000 would benefit from corneal transplantation, but only 1,200 sight-restorative corneal transplantations are performed annually.[6] In short, there is a huge deficit between supply and demand of organs and tissue suitable for transplantation. While some small portion of this deficit can be attributed to organ/tissue waste and export, most of it is the result of an ongoing inability to procure sufficient quantities (ie untapped capacity). This deficit, which is reproduced in virtually all countries around the world,[7] constitutes one of the most pressing problems facing China today, at least from a healthcare perspective for, as should be obvious from the above, a fully realised transplantation programme could improve the health and functionality of millions of people, with numerous knock-on effects.

This paper examines transplantation in China. While stem cell research, particularly embryonic stem cell research, may facilitate the development of personalised regenerative medicine and thereby eventually transform transplantation practices and programmes, this is unlikely to happen anytime soon. Thus, more traditional (conventional) practices will have to satisfy public health needs. As such, this paper focuses on the transplantation of whole organs (eg kidneys, livers, etc.). First, it explores the unique social context that is China, identifying the particular social and institutional character that is exposed, and suggesting how that interacts with, or is relevant to, the medical transplantation context. Second, it examines China's existing legal and ethical regulatory framework, evaluating how the institutions and

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1 P. Linden, 'History of Solid Organ Transplantation and Organ Donation' (2009) 25 Critical Care Clinics 165-184.

2 T. Chan, 'Donor Shortage in Organ Transplantation: Perspectives from Hong Kong' (2002) 34 Transplantation Proceedings 2558-2559.

3 Z. Liu *et al.*, 'Are We Ready to Utilize Non-Heart-Beating Donors for Clinical Allotransplantation in China?' (2008) 40 Transplantation Proceedings 1018-1020.

4 L. Zhang *et al.*, 'Knowledge and Willingness Toward Living Organ Donation: A Survey of Three Universities in Changsha, Hunan Province, China' (2007) 39 Transplantation Proceedings 1303-1309.

5 *Ibid*.

6 H. Guo, 'The Experts in Law Appeal for Developing Regulations on Human Oran Transplantation', Legal Daily, 1 June 2005.

7 In the UK, as of 31 March 2008, there were 7,655 patients on the active transplants list, and another 2,092 on the temporarily suspended transplants list, which figures can be contrasted to the 3,235 transplants that actually occurred: see NHS, *Transplant Activity in the UK: 2007-2008* (2008), available at https://www.uktransplant.org.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/transplant_activity_uk_2007-2008.pdf [Accessed 9 December 2008]. Of course, this is just one of any number of examples that could be used.

practices erected are responding to China's needs, identifying major regulatory themes and gaps, and, importantly, articulating the values claimed and exposed. Third, drawing on these values, it offers an alternative framework for meeting China's organ and human tissue needs, focusing on the key issues of oversight, procurement, and allocation. It concludes by offering some comments on how this 'Chinese' approach might be exported to other jurisdictions.

THE SOCIAL CONTEXT: INSTITUTIONAL AND ATTITUDINAL TRANSITION AND AMBIVALENCE

China's Uneven Socio-Economic Development and its Interaction with Health

China is a unique jurisdiction which straddles the ancient and the modern, the developing and the developed, the planned and the mixed/market. The current Chinese social context is characterised by rapid growth and transformation in a variety of sectors, including the academic,[8] economic,[9] and scientific sectors,[10] and by stasis and fragmentation in other sectors, most notably the healthcare sector.[11] Indeed, many key sectors, including the healthcare sector, are viewed merely as a means of supporting economic achievement by enhancing productivity and social stability.[12] Thus, the economic transformation (and the economic agenda) colours all others and cannot be ignored.

China has increased its development and production of goods, expanded external trade, initiated numerous overseas projects, and attracted significant foreign direct investment, realising an average annual GDP growth rate of 9.7%, and a 2005 trade surplus of some US$102 billion.[13] It has invested substantial sums in high-tech and biotech R&D, recently climbing to third largest spender on R&D (with stem cell research considered a leading field).[14] Moreover, it has maintained some public control of innovation through targeted spending (eg the 863 Plan,[15] the 973 Plan,[16] and others) and public sector

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8 C. Godwin, 'The Summer School in the Context of UK-China Science Relations', presented at the CAS-IPM / EGN China-UK Summer School, 'The Governance and Regulation of Emerging Biotechnologies', Beijing, 1-12 June 2009.

9 OECD, *OECD Reviews of Innovation Policy: China – Synthesis Report* (2007), available at http://www.oecd.org/dataoecd/54/20/39177453.pdf [accessed 28 July 2009].

10 B. Stembridge, 'Innovation Trends in China' (2006) at http://scientific.thomson.com/news/newsletter/2006-05/832540/ [accessed 2 August 2006].

11 UN Health Partners Group, 'A Health Situation Assessment of the People's Republic of China' (2005) available at www.wrpo.who.int/NR/rdonlyres/0267dce8-07ab-437a-8b01-03d474d922cd/o/hsa_en.pdf [accessed 29 August 2006].

12 J. Leung, 'Social Welfare in China' in A. Walker & C. Wong (eds.), *East Asian Welfare Regimes in Transition: From Confucianism to Globalism* (Bristol: Policy Press, 2005) 49-72. See also R. Peerenboom, *China Modernizes: Threat to the West or Model for the Rest?* (Oxford: OUP, 2007), who classifies economic reform as one of China's four main pillars of modernity.

13 L. Yueh, 'Patent Laws and Innovation in China' (2006) at www.economics.ox.ac.uk/research/wp/pdf/paper271.pdf [accessed 4 August 2006], W. Morrison, *Report for Congress: China's Economic Conditions* (Washington: Library of Congress, 2006), and TDC Trade, 'Market Profile on Chinese Mainland' (2006) at www.tdctrade.com/main/china.htm [accessed 7 September 2006].

14 H. Tomlinson & D. Adam, 'China Surges Ahead in Stem Cell Science' (2005) at www.guardian.co.uk/genes/article/0_1396905,00.htm [accessed 2 August 2006].

15 Also known as the National High-Tech Plan, and initiated in 1986, the 863 Plan saw some US$3 billion of public funding for basic and applied biotech research directed at one of China's most pressing health issues, malnutrition and food source security, focusing in particular on maize, rice, wheat, soybeans and cotton.

16 Also known as the National Basic Sciences Initiative, and initiated in 1997, the 973 Plan saw some US$302 million for basic research, with biotechnology and life sciences priority areas.

involvement in the commercialisation of outputs.[17] Such integrated strategies have contributed to Chinese companies becoming much more innovative and competitive (eg one such company became the first to obtain a licence for a recombinant gene therapy directed at head and neck cancer).[18]

Although this economic blossoming has had some positive impacts on healthcare,[19] a similarly robust and positive transformation has not been realised in the health sector. The Chinese healthcare system is fragmented, under-funded, and responding poorly/slowly to China's modernising efforts, which, as noted above, are creating pace and dynamism in other sectors.[20] Healthcare responsibility has largely devolved to the provinces, financing is decentralised to the lowest administrative level, and although healthcare spending has increased dramatically, under-investment continues, and public spending is outweighed by out-of-pocket spending (eg the latter constitutes 54%-60% of all healthcare spending).[21] There exist immense disparities in access to services between regions and economic strata, the different health insurance systems which exist for rural and urban populations are not integrated, and the system suffers from severe understaffing and a low level of quality-of-service-related regulation (eg ethics training is not yet the norm and many genetic practices have not yet undergone ethical-legal assessments).[22] Recent attempts to reduce spiralling costs, provide more community-based services and universal insurance coverage, and to focus on preventive medicine have been mostly unsuccessful.[23]

This fragile and unsettled system must address problems common to most developing countries (eg malnutrition, poor neonatal care, and inadequate immunisation against communicable diseases), while simultaneously responding to issues thrown up by rapid economic and social development, namely increasingly sedentary lifestyles (which lead to obesity and lifestyle related ailments), increasingly migratory/mobile populations (which increase the spread of communicable disease), and longer life expectancy (which increases the incidence and duration of non-communicable and chronic conditions such as heart disease, renal failure, cancer, and partial disability).[24] Addressing these problems is made all

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17 J. Huang & Q. Wang, 'Biotechnology Policy and Regulation in China' (2003), available at www.ids.ac.uk/ids/bookshop/wp/wp195.pdf [accessed 7 September 2006], and J. Keely, 'The Biotech Developmental State? Investigating the Chinese Gene Revolution' (2003) at www.ids.ac.uk/ids/bookshop/wp/wp207.pdf [accessed 7 September 2006].

18 Z. Li *et al.*, 'Health Biotechnology in China: Reawakening of a Giant' (2004) 22 Nature Biotech. Supp. DC13-DC18.

19 Economic strength has led to extensive research funding, and research on human embryonic stem cells, for example, has led to the production of hES-derived glandular structures for treating diabetes and Parkinson's disease, and the successful transplantation of hES-derived brain nerve cells: see M. Sleeboom, 'Stem Cell Research in China: An Intertwinement of International Finances, Ambition and Bioethics' (2002) 29 IIAS Newsletter 49, P. Cho, 'US Embassy Report: Human Embryonic Stem Cell Research in China' (2002) at www.usembassy-china.org.cn/sandt/stemcell.htm [accessed 2 August 2006], and M. Magistad, 'The Global Race for Stem Cell Therapies' (2005) at www.theworld.org/technology/semcell/03.shtml [accessed 2 August 2006].

20 See WHO, 'China: Country Cooperation Strategy' (2006) at www.who.int/NR/rdonlyres/e8be4438-924f-4193-89f3-b81822ac408c/o/ccsbrief_en.pdf [accessed 29 August 2006], and P. MacLeod & F. Fraser, 'Forget Cloning Sheep and Pay Attention to China' (1998) 159 C.M.A.J. 153-155.

21 See UN Health Partners Group, *supra*, note 11, UN, 'Advancing Social Development in China' (2005) available at www.unchina.org/115plan/english.pdf [accessed 29 August 2006], and UNICEF, 'At A Glance: China' (2006) available at www.unicef.org/infobycountry/china.html [accessed 7 September 2006].

22 H. Yang, 'The Social Responsibility of a Human Geneticist in China: A Personal Point of View' in *Proceedings of the Sixth Session of the IBC*, vol. II (Paris: UNESCO, 1999) 51-59, at 53.

23 Z. Dong & M. Phillips, 'Evolution of China's Health-Care System' (2008) 372 Lancet 1715-1716.

24 H. Jiang *et al.*, 'Major Causes of Death Among Men and Women in China' (2005) 353 N. Eng. J. Med. 1124-1134.

the more difficult by the widely dispersed and massive population the system has to serve (eg 1.307 billion people over 9.6 million km^2).[25]

What of transplantation within this system? As noted above, there are millions of Chinese patients suffering from conditions which would benefit from transplantation. Recognising this, local (institution-based) transplantation programmes expanded dramatically. However, central policymakers failed to take a guiding hand in this expansion, thereby neglecting to provide any unifying regulatory framework. As such, as with other elements of Chinese healthcare, transplantation practices, effectiveness, and availability all evolved very unevenly, not least because of physician apathy and the unavailability of ICUs, or, alternatively, the inability of ICUs to respond adequately to prevailing conditions and opportunities.[26] The result of this was (and continues to be) immense disparities in access to organs/tissue, deficiencies in clinical practice (ie quality of treatment and follow-up), widespread infringement of patient (donor) rights, the formation of an organ (black) market, and the growth of transplantation tourism (which prejudices Chinese patients).[27] Thus, despite the expansion in transplantation programmes, and the notional ready availability of organs (due to a vast population base), demand in China far outstripped supply, and continues to do so. Given this growing access gap, transplantation programmes began to rely on executed prisoners, including minors, as a source for most of the transplanted organs, which approach brought Chinese transplant medicine under intense international scrutiny and criticism.[28]

China's Evolving Value Position on Transplantation

As can be seen from the above, the existing Chinese organ/tissue deficit is the result of a variety of intertwined factors, all of which negatively impact on a core element of transplant medicine, namely procurement (ie: the effectiveness of supply-side activities). However, the above institutional and professional shortcomings are not the only impediments to improving transplant medicine in China. A further important aspect is that of public perceptions of, and attitudes toward, transplantation as a medical practice. Given our concern with values, it is important to explore in greater detail Chinese attitudes toward transplantation, an endeavour admittedly hampered by the relative lack of good evidence. Having said this, some evidence does exist and is supportive of some preliminary observations.

In a 1990 survey of 2,000 subjects in Hong Kong, 53% of respondents were personally willing to be cadaveric donors (7% expressed unwillingness), and 39% were willing to donate family members' organs (with 25% unwilling).[29] A 2005 review of all

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25 As noted by Q. Han *et al.*, 'China and Global Health' (2008) 372 Lancet 1439-1441, the scale of China's healthcare needs is vast (eg over 300 million smokers, 177 million hypertensives, and 140 million urban migrants subject to transport injury), the rate of change is rapid (eg what took a century in the west has taken decades in China), and the diversity of need is unparalleled.

26 See S. Rizvi *et al.*, 'Improving Kidney and Live Donation Rates in Asia: Living Donation' (2004) 36 Transplantation Proceedings 1894-1895.

27 J. Huang, Y. Mao & J Millis, 'Government Policy and Organ Transplantation in China' (2008) 372 Lancet 1937-1938.

28 *Ibid*. See also T. Diflo, 'Use of Organs from Executed Chinese Prisoners' (2004) 364 Lancet s30-s31, J. Watts, 'China Introduces New Rules to Deter Organ Trade' (2007) 369 Lancet 1917-1918, L. Tu *et al.*, 'China's New Regulation Exposes Organ Removal from Live Minors', Epoch Times, 26 March 2007, available at http://www.theepochtimes.com/news/7-3-26/53367.html [accessed 28 July 2009], and S. Biggins *et al.*, 'Transplant Tourism to China: The Impact on Domestic Patient-Care Decisions', Clinical Transplantation, 2009, DOI: 10.1111/j.1399-0012.2008.00949.x (online), who report that many foreign clinicians believe that the allowance of a transplantation tourist market has had a negative impact on domestic patient care decisions.

29 T. Chan, *supra*, note 2.

Hong Kong surveys conducted from 1990-2004 showed a trend toward a growing willingness to donate, combined with a reluctance to make donation decisions on behalf of family members.[30] A 2005 survey of donor families in Hong Kong suggested that families were often ambivalent, confused, and under stress at the time of decision, and that they desired both informational support (regarding cause of death, meaning of brain death, funeral arrangements and financial assistance), and emotional support (a good/safe decision-making environment with access to health professionals and potential follow-up).[31] In a 2006 survey of 434 university students in mainland China, 49.8% of the subjects were willing to be living donors (mostly for the benefit of family members), and 58.4% felt live donation would ease the organ shortage.[32]

All of these surveys, with their evidence of a willingness to donate, expose a commonly shared value of concern for, or 'solidarity' with, other humans; certainly family members, but also other vulnerable people or groups. This generalised concern for the wellbeing of others is supported by the Confucian concept of *ren*, which means loving people and caring for others, and it supports ethical imperatives to care for patients. It is an extension of the natural compassion that everyone feels (or should feel) toward others in view of the hardships and misfortunes of those others,[33] and it is in compliance with the 'noble values of respect … and mutual help' espoused by the State Council.[34] Another value concept supported by the surveys is that of 'reward for altruism'. For example, 48% of the respondents to the 2006 survey felt that partial compensation would effectively increase donor rates, and preferred this approach over purely voluntary or market based approaches.[35] In short, there was little affinity with purely altruistic donation, particularly for strangers, in part because the existing altruism-based system was viewed as having failed and therefore being inadequate. The increasing resonance of this value in Asia is not only demonstrated by the scholarship committed to it, but also by supportive statements from the Southeast Asian Bioethics Society, which accepted it as ethical where informed consent was present, coercion absent, donor care sufficient, third-party profiteers avoided, and fair compensation agreed.[36] Given the absence of any additional risk to donors, and of any evidence that such an approach would hinder (currently insufficient) cadaveric donation, some form of altruism-enhancing reward/compensation approach may be widely accepted.[37]

Of course, as both the ongoing organ shortage and low donation rates (as compared to claimed willingness rates) demonstrate, there are also important countervailing phenomena. One is level of ambiguity (and therefore uncertainty) around the appropriate definition of death. In particular, there is resistance to the reliance on brain stem death (as opposed to death measured by circulatory and respiratory cessation), particularly amongst certain religious groups.[38] A second countervailing phenomenon, a more expressly value-based one,

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30 B. Cheng *et al.*, 'An Overview of Attitudes Towards Organ Donation in Hong Kong' (2005) 7 HK J Nephrol 77-81.

31 Y-F. Tong *et al.*, 'Needs and Experiences of Hong Kong Chinese Cadaveric Organ Donor Families' (2006) 8 HK J Nephrol 24-32.

32 L. Zhang *et al.*, *supra*, note 4.

33 Y. Wang, 'Chinese Ethical Views on Emerging Biotechnologies', presented at the CAS-IPM / EGN China-UK Summer School, 'The Governance and Regulation of Emerging Biotechnologies', Beijing, 1-12 June 2009.

34 Quoted in C. Chan & G. Bowpitt, *Human Dignity and Welfare Systems* (Bristol: Policy Press, 2005) at 81.

35 L. Zhang *et al.*, *supra*, note 4.

36 E. Ona, 'Compensated Living Nonrelated Organ Donation: An Asian Perspective' (2000) 32 Transplantation Proceedings 1477-1479.

37 And for further argumentation on this, see L. de Castro, 'Compensating Organ Donors: Why Commercialisation and Exploitation are not Good Arguments' in SY. Song *et al.* (eds.), *Asian Bioethics in the 21st Century* (Tsukuba: Eubios, 2003) 132.

38 This is also the case in Japan. For more on this, see Z. Liu *et al.*, *supra*, note 3.

and one which is exposed by the surveys, is a deep respect for the physical integrity of the deceased person, or 'sanctification of the body'. The surveys highlight the continuing importance of traditional beliefs about rebirth; long enduring ideas about being reborn and therefore having to protect the integrity of the body make some people reluctant to be living or cadaveric donors and even more reluctant to make donation decisions on behalf of cherished family members (ie there is a reluctance to permit the removal of anything from the body lest it be missing upon rebirth).[39] Although often unarticulated, this belief is present and becomes more prevalent in times of crisis and loss.[40] Thus, while it has been challenged as inappropriate insofar as none of the major religions in Asia (Buddhism, Hinduism, Islam, Christianity) exhibit any hostility toward organ donation in the abstract,[41] and while it is somewhat contrary to the Confucian approach to personhood—personhood is said to begin at birth, endure in those with capacity for social relations, and end at death[42]—this sanctification position continues to influence people's conduct. Having said that, it does appear to be trending down as a decisive factor.[43]

This very brief and admittedly unsophisticated consideration of the social context underlying transplantation in China suggests that China (collectively and individually) is in a state of transition on many fronts, with concomitant value shifts (and conflicts). While a great variety (and complexity) of personal values and motivations will be relevant to making personal decisions about organ donation for oneself or one's family members, the evidence reviewed suggests that the values of (1) solidarity, (2) rewarded altruism, and (3) sanctified body/corpse integrity are widely shared. Their interaction (or rather competition), together with the foibles of, and burdens on, the existing healthcare system, have resulted in China experiencing a massive gap between demand and supply of organs and tissue, with the result that patients are deprived of life extension, and improved quality of existence, all of which have a concomitant knock-on effect for social wellbeing, healthcare costs, and productivity.

How have legislators responded?

THE REGULATORY RESPONSE: REACTIONARY AND COUNTER-PRODUCTIVE LEGISLATIVE INSTRUMENTS

China's Belated and Future Regulatory Responses

In the last decade, China has passed a variety of biomedicine regulations.[44] Those most relevant to transplantation are the *Regulation on Clinical Applications of Human Organ*

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39 For more on this belief, see X. Zhai & R. Qiu, *Introduction to Bioethics* (Beijing: Tsinghua University Press, 2005).

40 B. Cheng *et al.*, *supra*, note 30.

41 A. Vathsala, 'Improving Cadaveric Organ Donation Rates in Kidney and Liver Transplantation in Asia' (2004) 26 Transplantation Proceedings 1873-1875.

42 Confucianism and its approach to personhood is the most prevalent ethical approach in China: X. Zhai & R. Qiu, 'Ethical Issues at the Frontier of Science & Biotechnology' presented at the CAS-IPM / EGN China-UK Summer School, 'The Governance and Regulation of Emerging Biotechnologies', 1-12 June 2009.

43 B. Cheng *et al.*, *supra*, note 30. The persistence of this deceased-physical-integrity value as a practical barrier to donation is also lamentable given that bodies are almost universally burned in China (thereby destroying their integrity.

44 For example, China has promulgated the *Regulation for Protecting Human Genetic Resources 1998* (MOH and MOST), the *Regulation for Drug Clinical Trials 1999*, revised 2003 (SFDA), the *Regulation for Human Assisted Reproductive Technologies 2001*, revised 2003 (MOH), the *Principles and Technical Norms for Human Assisted Reproductive Technologies 2001*, revised 2003 (MOH), the *Ethical Guiding Principles for Human Embryonic Stem Cell Research 2003* (MOH and MOST), the *Regulation for Ethical Review of Biomedical Research Involving Human Subjects 2007* (MOH), and the *Regulation on Clinical Applications of Medical Technologies 2009* (MOH).

Transplantation Technologies 2006 (Clinical Application Regulations),[45] and the *Human Organ Transplantation Ordinance 2007* (HOTO).[46] The Clinical Application Regulations were the first transplant-related legal instrument in China. Always intended to be interim, they required transplantation institutions to register with the Ministry of Health, which would only certify them if certain scientific and ethical standards were met. They stipulated that every case should be submitted to an ethics committee for review and approval, and prior consent of both donors and recipients must be written and preceded by information. Additionally, organ trading was prohibited, a direct response to the international outcry over past practices (eg: transplantation tourism and organ procurement from prisoners).

The HOTO is both more recent and more comprehensive than the Clinical Application Regulations. Intended to promote health, ensure quality healthcare, and safeguard the rights and interests of patients,[47] it is directed at whole or partial organ transplantation (as opposed to cell, tissue, marrow or corneal transplantation, or cellular therapies).[48] First and foremost, the HOTO bans the sale of organs and related activities,[49] reiterating that donation should be unpaid, voluntary and not induced or coerced.[50] Prior written consent must be obtained from both donor (or the family of a deceased donor) and the recipient, and living donors must be over 18 years-old and must be a member of the recipient's family.[51] Medical institutions which conduct transplantations must register with the provincial health administration and meet certain qualifications relating to equipment, management practices, and ethical oversight.[52] Unregistered institutions are prohibited from performing transplantations and qualified transplant physicians are not permitted to practice in unregistered hospitals.[53] Every transplantation operation must be preceded by an Institutional Review Board review.[54] Violations of the HOTO constitute a crime which could result in confiscation of derived income, fines and license revocation for institutions, and fines, transplant license revocation, and professional sanctions (including expulsion from the profession) for individuals.[55]

Unfortunately, the HOTO, as it presently exists, suffers from a number of shortcomings, not least those relating to the availability of infrastructure to enforce it (and indeed the political will to do so).[56] Political and healthcare system capacity concerns aside, the HOTO fails utterly to note (or to apparently take heed of) the reality of an ever-widening gap between supply and demand of tissue and organs for transplantation. Of particular importance to this situation, there is very little engagement with eligibility to be a donor; the definition of death and specification of eligibility can dramatically expand or shrink the potential donor pool. This is problematic given the Chinese ambiguity around the acceptance of brain death (and the concomitant advocacy from some corners of cessation of circulation

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45 Decree No. 94 (2006), Ministry of Health, in force 1 July 2006.

46 Decree No. 491 (2007), State Council, in force 1 May, 2007.

47 Article 1, HOTO.

48 Article 2, HOTO.

49 Article 3, HOTO. Article 26 makes such conduct a crime and stipulates penalties.

50 Article 7, HOTO.

51 See Articles 8, 9 and 10, HOTO. This condition has caused a number of controversies where willing non-related patients have wanted to exchange organs: see Xinhuanet, 'Kidney Transplants Expose Regulation Holes', China Economic Net, 13 January 2008, available at http://en.ce.cn/National/Local/200801/13/t20080113_14208052.shtml [accessed 22 october 2009].

52 See Article 11-15, HOTO. Additionally, such registration will be cancelled if certain success and survival rates are not met: see Article 17, HOTO.

53 See Articles 11 and 13, HOTO.

54 Article 11, 17 and 18, HOTO.

55 Articles 25-31, HOTO.

56 Y. Wang, *supra*, note 33.

and respiration as the standard for death).[57] Additionally, very little is said about organ procurement; aside from references to the need for informed consent and voluntariness, and for living donation to be aimed at someone in close relational proximity, donation is not regulated in detail. In particular, there is no direct prohibition of the use of prisoners, or, alternatively, clarification of how and under what circumstances organs might be obtained from prisoners, and this might have been warranted given the (troubled) history of their use, their ongoing use, and their particular institutional setting.

In short, the HOTO might fairly be characterised as a reactionary response to an international outcry which is wholly inadequate to address the medical/social/moral problems to which it is directed; while it addresses the very important issue of clinical standards, it fails to address (or improve) other key issues, including public education, physician education, procurement enhancement, etc. Indeed, it has been reported that the HOTO has had the unenviable consequence of decreasing the number of cadaveric transplants by more than two or three fold, as well as reducing the number of institutions approved for performing transplants.[58]

It has recently been reported that China is planning to revise its governance of transplantation to bring it more in line with international standards.[59] As such, and in anticipation of this, one should highlight the *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation* ('WHO Guiding Principles'),[60] which state as follows:

- Organs may be removed from the bodies of deceased persons for the purpose of transplantation if (a) any consent required by law is obtained, and (b) there is no reason to believe that the deceased person objected to such removal, in the absence of any formal consent given during the person's lifetime.[61]

- Physicians determining the death of a donor should not be directly involved in organ removal, transplantation, or care of the recipient(s).[62]

- Cadaveric donation should be developed to its maximum potential, but adult living donors (not minors) are also acceptable, though they should be genetically related to recipients, and must give informed, voluntary consent.[63]

- Organs should be donated altruistically and without monetary payment other than reimbursement of reasonable and verifiable expenses, and the offering, advertising, brokering, or purchasing of organs should be banned.[64]

- If physicians or other carers have concerns about exploitation, coercion, or payment, they should refuse to perform the transplantation, and neither they nor their institution should receive payments exceeding a justifiable fee for services.[65]

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57 Z. Liu *et al.*, *supra*, note 3.
58 J. Huang, Y. Mao & J Millis, *supra*, note 27.
59 *Ibid*.
60 Document EB123/5, WHO Executive Board, 26 May 2008.
61 Principle 1.
62 Principle 2.
63 Principles 3 and 4.
64 Principles 5 and 6.
65 Principles 7 and 8.

- Organs should be allocated according to clinical criteria and ethical norms, not financial or other considerations, and rules should be equitable and transparent.[66]

- Monitoring, recording and oversight are necessary to protect quality, safety and efficacy, and management systems must be transparent and open to scrutiny while ensuring personal anonymity and privacy of donors and recipients.[67]

These WHO Guiding Principals were revised in 2008 due, in part, to concerns over organ trafficking, with which China was deeply implicated, and it is anticipated that they will serve as a model for reforms. In fact, their previous manifestation served as a reference point for the HOTO, and it has been noted that such international guidelines are the result of communication and negotiation among experts from countries and cultures from around the world, including China, and should therefore be complied with, having reference to the cultural context when implementing them.[68]

China's Legislatively-Advanced Value Concepts

As with the social setting, it is important to consider at least briefly the value concepts exposed by both the domestic and international regulatory instruments. What core values are exposed by the HOTO and the WHO Guiding Principles? And are they compatible with those suggested by the social setting?

Foremost, are concerns for collective and individual patient 'safety' through multiple references to performance, facility and equipment standards, and to effective management systems. Additionally, 'autonomy', or respect for individual choice, is advanced through demands for the informed consent of both donors and recipients. Both instruments espouse 'altruism' via directions that donors be unpaid. And, finally, 'equity' is advanced as important, at least in the WHO Guiding Principles, through references to allocation according to clinical indications and ethical norms. While these values do not mirror those evidenced in the social setting more broadly, they are by no means incompatible.

Some further relevant values or concepts might be derived for the Chinese context from select provisions of the *Constitution of the People's Republic of China* (Constitution),[69] which specifically tasks the state with promoting 'high ideals' and 'ethics'.[70] All of the myriad provisions which structure the socialist system harken to a belief in 'social solidarity' characterised by mutual respect, mutual reliance, and harmony.[71] This concept of solidarity is bolstered by the entrenchment of a state duty to provide universal health services and welfare support.[72] There is also some foundation for 'equality' as a moral/social value in references to everyone being equal under the law and under the socialist dictatorship, and to all nationalities within China being equal.[73] There is a rhetorical affinity for 'autonomy' in provisions which extend freedom of political action, speech, religion, and privacy, which erect the inviolability of physical integrity, and which permit the pursuit of scientific and

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66 Principle 9.
67 Principles 10 and 11.
68 X. Zhai & R. Qiu, *supra*, note 42.
69 Adopted at the 5th Session of the Fifth National People's Council, 4 December 1982, amended 1988 and 1993, available at http://www.hkhrm.org.hk/english/law/const01.html [accessed 29 July 2009].
70 Article 24, Constitution.
71 Chapter I, Constitution.
72 Articles 21, 44 and 45, Constitution.
73 Articles 1, 2, 4, 33 and 48, Constitution.

creative endeavours.[74] Finally, there is also a strong recognition of 'duties' on the part of the individual toward others and toward the state.[75]

This assessment of the key legal instruments relevant to transplantation serves primarily to emphasise that legal responses in China have been late and inadequate, particularly with respect to improving organ and tissue supply, networking actors, and ultimately helping patients desperate for effective care and thereby alleviating healthcare system burden. It also highlights the value concepts that underlie these instruments, and the Chinese legal and social system more generally. It makes clear that existing regulatory efforts have not engaged particularly well with (ie have not clearly recognised and effectively advanced) the social values apparently relevant to the transplantation setting, nor indeed some of the broader values contained in the Constitution.

We suggest that legislators must more effectively and creatively link social values, Constitutional values, and regulatory responses to particular medical problems, finding those areas of value convergence and adopting policy positions that vindicate those values while solving the particular (medical) problem to be addressed. Obviously, this represents an impressive but not insurmountable policy-making challenge. Our analysis, which relies on only preliminary social evidence, suggests that future reform of the Chinese approach to transplantation should have some regard to, and should advance where possible, concepts of (1) safety, (2) solidarity and altruism, (3) equity/equality, (4) autonomy, and (5) duty-fulfilment.

What might such a regime look like?

THE FUTURE: POSSIBILITIES FOR A MORE EFFECTIVE TRANSPLANTATION REGIME

All told we might highlight several primary reasons for the shortage of organs and tissue in China: (1) the general size of the population and the volume of demand it creates; (2) a traditional cultural antagonism toward division of the body; and (3) the complete inadequacy of the existing policy and regulatory framework to reverse organ deficit trends and promote greater commitment to donation. Focusing on the latter condition—the policy and regulatory framework—the remainder of this paper explores some reform possibilities aimed at increasing organ and tissue transplantation and improving transplantation management, bearing in mind the above driving values.

At the outset, we note that the framing of the issue is of great importance. We start from the premise that transplantation, as a proven and cost-effective treatment option where it has been sufficiently developed,[76] is (or should be) a favoured healthcare response to a variety of chronic and otherwise terminal conditions. Used maximally, it could improve the health, functionality, productivity, and enjoyment of life of millions of people, both in China and beyond, and in doing so, could have a transformative effect on healthcare delivery and healthcare system efficiency. One might characterise the chronic shortage of transplantable

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[74] Articles 33, 34, 35, 36, 37, 39, 40, 41, 47, Constitution. Note that, from a practice perspective, this autonomy—this decision-making space-creation—is less purely individualistic than that to which we are accustomed to claiming in the West; but family and community-influenced decision-making liberty is clearly espoused.

[75] Articles 33, 42, 46, 49, 51, 52, 53, 54, 55, 56, Constitution.

[76] Numerous studies have demonstrated that kidney transplantation is cheaper than, and improves longevity over, dialysis, as is the case with other forms of transplantation, such as liver and heart: see W. Winkelmayer *et al.*, 'Health Economic Evaluations: The Special Case of End-Stage Renal Disease Treatment' (2002) 22 Med Decision Making 417-430, R. Adam *et al.*, 'Evolution of Liver Transplantation in Europe' (2003) 9 Liver Transplant 1231-1243, D. Taylor *et al.*, '2006 Report of the International Society for Heart and Lung Transplantation' (2006) 25 J Heart Lung transplant 869-879, and others.

organs and tissue as a purely social problem, but we prefer to characterise it as an acute moral issue; an unethical and unjust state of affairs that represents a fatal shortcoming of the healthcare system as it currently exists.[77] By framing the issue as a pressing moral matter, one strengthens the imperative to remedy it, and expands the range of possible (defensible) mechanisms for doing so, the ultimate aim being to promote human wellbeing and advance human *dao*, which lies in 'a good beginning and a good end'.[78]

First, we reiterate that it is advisable that a comprehensive legislative framework be adopted. The benefits of this include the erection of enforceable boundaries, the provision of concept clarity for transplantation actors, the potential creation of greater public understanding and acceptance of transplantation, and satisfaction that all actors are operating within considered bounds. In addition to addressing risk, safety, and good clinical practice, it must positively define key terms (based on sound medical evidence). In particular, it must define 'living donor', outlining the circumstances under which organs/tissue might be taken from conscious individuals, including minors and those in state custody. It must define 'brain dead donor', offering a clear, practical and internationally accepted definition of brain death. And less controversially, it must define 'non-heart-beating donor'. Like the present law, it should also address technical standards relating to the facilities and equipment used, providing for institutional application for transplant eligibility, site inspections, certification, and review/oversight. Finally, it should also stipulate standards for primary and support staff, erecting a licensing process comparable to that relating to institutions.

We now turn to more specific oversight, procurement, and allocation issues. The solutions offered are grounded on our weighing of three factors: (1) the recognition of a moral imperative to improve public health through greater access to, and improved effectiveness of, transplant medicine in China; (2) the desire to advance some of the values (as we understand them) relevant to the transplant setting, particularly solidarity, rewarded altruism, safety, equity, and autonomy (in diminishing order of importance); and (3) the consideration of approaches that have proven effective in other jurisdictions (and which might not be completely anathema in China). It is our belief that the more comprehensive regime offered below would better vindicate the values relevant to this setting.

Oversight

A national Transplant Coordination Service (TCS), organised into central, regional and local/institutional branches, should be created so that trained and motivated transplantation experts could manage and advance transplantation medicine in China. The central/national Secretariat would (1) serve as the interface between the national government and the transplantation community, (2) set broad/national transplantation policy (including conducting public engagement exercises), and (3) erect and keep current national technical standards (through the hosting of expert consensus conferences). The regional branches would liaise with provincial governments and hospitals, and would additionally serve as the oversight arm of the TCS, certifying professionals as eligible transplant practitioners, licensing hospitals as transplant institutions, and recertifying their status through site and records inspections. They would audit institutions and practitioners for compliance with ethical allocation practices and generally ensure compliance with the statutory scheme. When breaches are alleged, either through independent inspections or patient complaints, they would investigate and determine whether to recommend prosecution. The local/institutional

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[77] Its moral foundation has also been recognized by others: see F. Cantarovich, 'Reducing the Organ Shortage by Education and by Fostering a Sense of Social Responsibility' (2003) 35 Transplantation Proceedings 1153-1155.

[78] Xun Zi, 313-238 BCE. For more on Xun Zi, see http://www.iep.utm.edu/x/xunzi.htm.

element of the TCS would comprise individual Transplant Coordinators; physicians and nurses acting on a part-time basis outside of their medical duties and reporting to their respective regional branches.[79] A TCS would go a long way toward educating and obtaining evidence from the public, thereby permitting better, evidence-based policies in the future. Through its monitoring and enforcement of transplant standards, it would enhance patient safety, a value already explicitly considered of vital importance. It would also make transplant medicine more transparent and responsive, and therefore more democratic.

Procurement

Procurement, if it is to be effective, is a complex and costly undertaking. However, given China's stated desire to improve healthcare and further economic development, it is a cost worth bearing and will, in the long term, save significant healthcare yuan. We suggest that if the Chinese transplantation programme hopes to close the gap between supply and demand (and perhaps one day meet demand),[80] it must adopt an integrated, multi-pronged approach to organ/tissue procurement which includes: (1) an intense healthcare professional education programme for all physicians and nurses; (2) a concerted and ongoing public education and promotional campaign; (3) the formation of a national transplant coordination service; (4) a national opt-out policy for cadaveric donation; and (5) a rewarded donation system for living donations.

Healthcare Professional Education: As noted above, there appears to be a certain level of ambivalence amongst healthcare professionals with respect to transplantation. Some of this may stem from traditional beliefs, but much of it probably stems from a poor or incomplete understanding of the costs, benefits, risks, and long-term consequences of transplantation for patients and for public health more generally, as well as on a general lack of technical support to effectively facilitate transplantations in the clinical setting. In addition to an increased focus on transplantation as a part of general medical education, all practicing physicians and nurses, especially those working in ICUs, Emergency Units, and Palliative Care Units,[81] should undergo mandatory continuing professional development training (in person and virtual/online) relating to transplantation. In addition to being informed about the value of transplantation and its importance to public health and national goals, training should focus on donor identification (which must occur early), donor screening (so disease transmission or infection are minimised), donor maintenance (so that organs are obtained in a usable state), sensitive physician-patient/family interaction (so a facilitative environment is created and information can be better shared and assimilated), and organ retrieval (best practices for removing, handling, preserving/storing, and transporting organs).

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[79] Parenthetically, the formation of an institution expert in transplantation matters would, presumably, enhance China's ability to tackle the social, ethical and technical issues raised by xenotransplantation if and when it becomes a more viable healthcare option.

[80] It has been claimed that, at least in some jurisdictions, there appear to be sufficient deaths under suitable circumstances to satisfy annual organ demand if collection rates are adequate: K. Obermann, 'Some Politico-Economic Aspects of Organ Shortage in Transplant Medicine' (1997) 46 Soc. Sci. Med. 299-311.

[81] For more on the value of 'marginal donors' like the elderly, minors, diabetics, those with ischemia or infection, and so on, see G. Abouna, 'Organ Shortage Crisis: Problems and Possible Solutions' (2008) 40 Transplantation Proceedings 34-38.

Public Education/Promotion: Multi-media public education and promotional campaigns, both national and regional,[82] should be undertaken on an ongoing or rolling basis. A general campaign, realised through print, radio, television, and web media, should advance the following concepts and messages:[83]

- every individual bears duties grounded in solidarity and altruism to others in society and to the state;
- duties extend to obligations to contribute to personal and public health and to the wellbeing of others, thereby improving national productivity;
- transplantation is an important and integral part of effective modern healthcare and is contrary neither to any major religion, nor to traditional ethics;
- every member of society is a potential donor and recipient (ie appeals to enlightened self-interest might highlight that the sharing of a personal resource, either during their life or after death or both, that is unique, may also benefit them in their lives);
- clinical and social outcomes consequent to successful transplantations are typically favourable (and specific evidence might be provided);
- the state and medical institutions are concerned with patient and public health, and risks to participants will always be minimised through strict safety measures and oversight.

This general campaign should be supplemented by campaigns targeting specific audiences. In particular, young people should be reached and encouraged so that health solidarity and transplantation/donation may become a part of the national social fabric.

Transplant Coordination Service: The TCS would take part in the proposed professional education and public promotion campaigns, bringing its unique perspective and evidence to bear, and it might also provide a 24-hour transplantation telephone hotline for those seeking information.[84] Its activities would expand the number of facilities capable of undertaking transplantations, and it could thereby facilitate (and coordinate) equitable organ sharing between institutions. At the hospital level, individual Transplant Coordinators, rather than treating physicians or nurses, could continuously monitor potential donors and approach patients and families about donation and transplantation.[85] They could provide information to individuals, assist in patient identification, articulate and resolve potential conflicts between being a patient and a potential donor, obtain consent (where applicable), coordinate the various actors involved in performing transplantations, and ensure the provision of adequate follow-up to both recipient and donor (if living) or family (if cadaveric).

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82 Such a 2-tiered approach is necessary so that nuances in local character and local reasons for suboptimal donation can be addressed, whether they are sociocultural, religious, or otherwise: see S. Rizvi *et al.*, *supra*, note 26.

83 See T. Chan, *supra*, note 2, F. Cantarovich, *supra*, note 77, and others.

84 Such a hotline has proved a very useful resource in Spain: see R. Matesanz & B. Dominguez-Gil, 'Strategies to Optimize Deceased Organ Donation' (2007) 21 Transplantation Reviews 177-188.

85 It has been reported that the Hong Kong Transplant Coordination Service, established in 1988, has enjoyed great success, raising the procurement rate from 10% to 40%: T. Chan, *supra*, note 2.

Opt-Out System (Cadaveric Donation): A nation-wide opt-out system for cadaveric donation should be instituted whereby every member of society is automatically a contributor to transplant medicine.[86] Thus, unless one specifically opts-out via a written form provided to a TCS coordinator and entered onto a central registry maintained by the TCS, one is automatically a member of the donation scheme such that when one dies, either naturally or by an accident, any organs and tissue of suitable quality are made available to patients within that region. Those who opt out would be issued an opt-out card to be carried on their person. Such an approach, when integrated with the other proposed actions, should dramatically increase organ and tissue availability, as has occurred in Spain.[87] From a value perspective, this approach recognises the greater social embeddedness that individuals in China have as compared to those in many Western states; individuals typically maintain closer ties with family and/or community such that, in the medical context, families (and sometimes communities) are involved in the process of giving consent, and families often provide essential care and emotional and financial support.[88]

While some will obviously complain that an opt-out approach diminishes, or is incompatible with, autonomy, we argue that it rather preserves autonomy and respect for the person insofar as every individual has the right, at any time, and after the consideration of as much or as little information as desired, to make an 'informed choice', to express that choice, and to have both respected. Ultimately, it strikes a reasonable balance between individual choice and promotion of the public good.[89] It is impossible to say who might object to an opt-out approach. This is an area which demands greater empirical work in China. But an opt-out approach would certainly have to overcome the traditional 'sanctified bodily integrity' value outlined above. Doing so would be one responsibility of the public education/promotion campaigns, but there is clear precedent of old beliefs being reinterpreted in response to new technologies, and ample support for this as an appropriate cultural and ethical undertaking. For example, it has been argued that filial piety must not be interpreted in a fundamentalist manner; it must be interpreted in keeping with *xiao* (to love, respect and care for parents) and *ren* (to love and care for and do good to others), which, in the modern context, support practices such as transplantation which are directed at treatment, and which outweigh old approaches to bodily integrity.[90]

Rewarded Donation System (Living Donation): It is fair to characterise live organ/tissue donation as an intimate form of social interaction which should result in some form of

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86 This is also sometimes called a 'presumed consent' approach. We prefer not to use 'presumed consent' because this is an unhelpful fiction; we are not presuming consent, we are disposing of the need for consent, and extending to individuals and families the possibility of exercising 'informed refusal' through the act of withdrawal.

87 We caution that an opt-out approach alone is unlikely to substantially increase organ procurement rates: see H. Low *et al.*, 'Impact of New Legislation on Presumed Consent on Organ Donation on Liver transplant in Singapore: A Preliminary Analysis' (2006) 82 Transplantation 1234-1237, A. Rithalia *et al.*, 'Impact of Presumed Consent for Organ Donation on Donation Rates: A Systematic Review' (2009) 338 BMJ a3162, and others.

88 X. Zhai & R. Qiu, *supra*, note 42. Having noted that, it is conceded that many western countries have adopted opt-out schemes, including Austria, Belgium, Spain, and Sweden, with varying degrees of success.

89 This has also been argued with respect to opt-out approaches to biobank information access: see M. Liu, X. Zhai & R. Qiu, 'Biological Information of the Informed Consent of the Treasury Issue' (2009) 10(2) Chinese Medical Ethics, available at http://translate.google.co.uk/translate?hl=en&sl=zh-CN&u=http://c.wanfangdata.com.cn/periodical-zgyxllx.aspx&ei=FoRxSv2zF5yRjAey5_ChDA&sa=X&oi=translate&resnum=1&ct=result&prev=/search%3Fq%3DLiu,%2BZhai%2BQiu%2B%2522Chinese%2BMedical%2BEthics%2522%2B2009%26hl%3Den%26sa%3DN%26start%3D10 [accessed 30 July 2009].

90 See R. Qiu, 'The Tension Between Biomedical Technology and Confucian Values' in J. Tao (ed.), Cross-Cultural Perspectives on the (Im)Possibility of Global Bioethics (Dordrecht: Kluwer, 2002) 71-88.

reciprocity.[91] In short, some benefits should be enjoyed by all participants (eg the public, the recipient, and the donor), and this seems to be the most fair and equitable approach (much more so than purely altruistic donation, which has proven wholly incapable of meeting demand).[92] While it has been claimed that the near universal rejection of a commercialised organ trade is gradually eroding,[93] it remains a controversial and, to many, an unpalatable option for increasing procurement rates.[94] As such—and given the existing Chinese (and international) rejection of organ markets,[95] as well as our touchstones of duty, solidarity, and rewarded altruism—a non-market approach to living donation is favoured. The survey evidence suggests that some recognition is warranted. This recognition could come in several forms, some of them compensatory, and it might include the following:

- Social Recognition: While one might hope for donation decisions to be purely solidaristic, it is not necessary to demand unbridled altruism of people, and its absence need not taint the act. Recognition might take several forms, from letters of appreciation from government and/or recipient (anonymised or not), to certificates of special recognition from the government and/or health authorities, to inclusion on a publicly searchable national list of live donors (for those wishing to waive their privacy rights).

- Enhanced Organ/Tissue Eligibility: Live donors, or a designated member of their immediate family, might automatically become eligible for 'enhanced consideration' should they develop a need for a transplantable organ or tissue. Their particulars could be entered onto national and regional registries until such time as they might have to enter a waiting list for a specific transplant, at which time they would be ranked as if they had been entered on the date of their donation.

- Improved Health Insurance Coverage: Live donors, or a designated member of their immediate family, might automatically become eligible for improved health insurance, a reward which could have great significance in China, where health insurance coverage is unevenly enjoyed and where many healthcare costs are born by patients out-of-pocket.

- Related Expenses: Live donors should receive financial compensation in the form of paid travel (and, if necessary, hotel) expenses for pre-op testing and post-op follow-up visits to the hospital, paid nutrition allowances for days spent travelling, wage continuation coverage for the duration of their convalescence, and a nominal, legislatively set financial award for the pain and inconvenience they will suffer as a result of surgery. This compensation might be contributed to by the state and by the private insurers of employers and hospitals.

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91 This appears to be the position in Europe: M. Schweda & S. Schicktanz, 'Public Ideas and Values Concerning the Commercialization of organ Donation in Four European Countries' (2008) 68 Soc. Sci. Med. 1129-1136.

92 In fact, demands for improved social recognition of donors is not new: see R. Veatch, 'Routine Inquiry About Organ Donation: An Alternative to Presumed Consented' (1991) 325 New Eng J Med 1246-1249.

93 M. Schweda & S. Schicktanz, *supra*, note 91. Iran permits organ sales: see A. Daar, 'The Case for a Regulated System of Living Kidney Sales' (2006) 2 Nature Clin. Nephrology 600-601. And see C. Erin & J. Harris, 'An Ethical Market in Human Organs' (2003) 29 JME 137-138, who advocate a brokered market approach.

94 See these studies: M. Schweda & S. Schicktanz, *ibid*, and C. Mehmet *et al.*, 'How to Improve Organ Donation: Results of the ISHLT/FACT Poll' (2003) 22 J Heart Lung Transplant 389-410.

95 See Article 3, HOTO, and Principles 5 and 6, WHO Guiding Principles.

This multiple reward system, built into the law, could reverse trends with respect to availability of quality transplantable organs from living donors (which are inarguably the best organs and the most likely to result in successful and long term health outcomes).[96]

Allocation

Aside from cases where a live donor's organ is donated to a specified patient, donated organs (whether from living doors or cadavers) are properly classified as 'public goods' over which the community has authority and control, not the donor, the physician, or the hospital.[97] This makes allocation a public concern. Where public knowledge and confidence exists with respect to allocation criteria and practices, procurement from both living and cadaveric donors might be enhanced; certainly the opposite—dissatisfaction with practices—can lead to diminished public support and reluctance to donate.[98] Procurement enhancement aside, allocation is a key site for the realisation of social justice and the practical operation of medical ethics. As such, allocation must be addressed in the legislative framework, both generally, through the articulation of broad guiding values such as fairness and equality, and specifically through the enumeration of acceptable decision-making criteria.

While allocation decisions must be seen as just/fair and equitable, perceptions of what constitutes justice and equity may shift over time. Thus, the statutory criteria—or 'decisional factors'—should be ranked by the TCS, in cooperation with the medical community, and fashioned into an ethically defensible and practical decision-making tool which is made public. Some relevant criteria include:

- histocompatibility;
- demonstrated past lifestyle;
- age of patient;
- duration patient has been on the national waiting list;
- existing quality of life of patient and life expectancy absent transplantation;
- urgency of need;
- anticipated quality of life and life expectancy post transplantation.[99]

Each criterion should be given a narrow range of potential scores so that clinical cases can be compared and decisions justified (to the individual and the public).[100] With some minor adjustments to rank and weight, these factors are relevant to most transplantable tissue. Thus, these criteria, regularly revisited, together with the maintenance of regional and national waiting lists, and agreed principles around a national organ sharing scheme (so that regions

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96 See G. Abouna *et al.*, 'The Living Unrelated Donor: A Viable Alternative for Renal Transplantation' (1988) 20 Transplantation Proceedings 802-804, and more.

97 And such has been widely accepted for some time: see J. Childress, 'Ethics and the Allocation of Organs for Transplantation' (1996) 6 Kennedy Inst Ethics J 397-401.

98 See T. Koch, 'Normative and Prescriptive Criteria: The Efficacy of Organ Transplantation Allocation Protocols' (1996) 17 Theoretical Medicine 75-93.

99 We recognise that this is a controversial factor, and that choosing between patients is a complex endeavour, which we do not have the space to explore here. Suffice to say that, it goes on all the time, and it is advisable to offer rules for such ranking decisions.

100 Past cases of perceived inequity in the allocation decisions (in the west) have demonstrated that the public cares about such matters, and recent studies have shown that people are prepared to engage with difficult ethical questions in the transplant allocation context: see J. Stahl *et al.*, 'Balancing Urgency, Age and Quality of Life in Organ Allocation Decisions – What Would You Do? A Survey' (2008) 34 J Med Ethics 109-115.

that might have acted competitively might better cooperate to the betterment of ethical outcomes and for the greater good), might significantly advance transplant medicine in China.

Summary

First, while we have focused on the legislative element, we have envisioned a legislative regime that supports a variety of mechanisms—some administrative, some educational, and some legal—to achieve the desired end. It is a joined-up approach structured by a legislative scheme, and implicating the criminal law, but only peripherally. Second, while it faces some challenges in the Chinese cultural context, the fluidity of that context must be recognised, and in particular the decline of practices/beliefs which might be explicitly resistant to the regime offered. Third, while the cost of such a scheme would not be negligible, we believe it would, in the long run, be more cost-efficient than many current non-transplantation-based options. Further, it is more readily available in that it does not rely on the (future) perfection of expensive high biotechnologies that are still in the developmental phase (eg stem cell therapies). As for how the costs of the scheme would be met, that is a political question incapable of being addressed in the present work. Finally, while one would hope the system would reach all corners of China, geography is a problem; it might have to develop in the more financially secure and culturally cosmopolitan east, and spread from there.

CONCLUSION

Conditions resulting in organ degradation and failure (and concomitant transplantation needs) are serious burdens on public health systems, on families, and indeed on ailing patients, in China and elsewhere. In many cases, transplantation represents the best treatment with respect to functionality, productivity, and cost-efficiency. As such, while transplantation is not a 'cheap' component of healthcare, it should be a key pillar of modern healthcare responses in China and elsewhere; transplants need to be more widely available, more quickly obtainable, and more confidently/safely receivable.

The integrated regime sketched out above can meet these needs. Importantly, it relies on, and advances, values that are either clearly embedded or widely claimed in China.[101] One obvious victim is the traditionally grounded sanctification of the body, but this value is both widely lamented and diminishing in relevance, and so might properly be transitioned out of the public conscience via the public education and promotional campaigns. Further empirical research is needed with respect to opinions and attitudes toward donation and transplant governance in (mainland) China, as well as the state of xenotransplantation and artificial organ transplantation, and social acceptance of same. Armed with such evidence, the system can be further tweaked to better reflect Chinese ideals.

While this regime was fashioned with a view to the Chinese context, we believe that many elements of the offering are transferable to other jurisdictions, including Western ones. Although the solidarity value and the idea of duties are not as strongly felt in the West, we note that Western welfare systems are grounded on solidarity, and that there is a growing call for the better articulation and realisation of duties in health and other contexts. In any event, the recognition of a broader base of values in Western countries may serve to increase the positive response to transplantation by diverse communities within such countries (eg

[101] It is important to note that we do not erect and deploy the values identified in a principlist manner. We are not suggesting that they should or must inform all Chinese medical decisions. Rather, we believe there is evidence that these broad values exist and we have drawn on them where we think appropriate in support of a regime we believe would advance healthcare.

Canada, the UK and US all have large Chinese and other immigrant communities which might respond favourably to a regime which better or more explicitly draws on values resonant in those communities).[102] In short, we do not see the value-base of this scheme as being a great hindrance to exportation, and we suggest that exportation of at least core elements is important to promoting international harmonisation (if not standardisation), and therefore broadly improving transplant medicine outcomes.

As a parting comment, we must stipulate that the key to the successful improvement of transplant medicine in China and elsewhere is the adoption of an integrated and multi-pronged approach; partial responses will likely result in little net improvement. The ultimate objective, whether in China or beyond, should be to realise the Confucian ideal of *xiaokang*, the 'well-off society'.

[102] We suggest that one avenue for improving response rates in such communities is to generate more and better evidence of the value positions and practices within those communities, both in the host country and the country of origin.